November 17, 2022

Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Pl, HFV-1
Rockville, MD 20855

Re: FDA CVM Regulation of Animal Foods with Certain Types of Claims (FDA-2022-N-2015-0001)

The Food and Agriculture Climate Alliance (FACA) welcomes the opportunity to provide comments to FDA on the regulation of animal foods with certain types of claims. FACA consists of more than 80 organizations representing farmers, ranchers, forest owners, agribusinesses, manufacturers, the food and innovation sector, state governments, sportsmen and sportswomen, and environmental advocates. Our organizations have come together to develop and promote shared climate priorities.

FACA supports innovative and voluntary solutions to reduce greenhouse gas (GHG) emissions, including methane. In this context, our organizations are seeking enactment of policy solutions that will help facilitate the reduction of methane emissions resulting from enteric fermentation in ruminant livestock. Enteric emissions directly from the cow currently account for roughly one third of all GHG emissions from dairy farms, for example, presenting an important area of opportunity.

Changes in feed composition can directly or indirectly reduce enteric emissions resulting from livestock. Feed additives can significantly improve digestibility and may alter production pathways of enteric methane emissions. Some of these additives are already approved for use in the European Union, Brazil, Australia, Chile, and most recently, Canada. Growing research indicates that feed additives can reduce enteric methane emissions by 30% or more.

However, despite calls for emissions reduction efforts across the agricultural supply chain, FDA has not currently approved any feed additives to meet this need. Current regulatory priorities, and unclear policy surrounding products that affect the gastrointestinal tract are perceived to delay market approval and in turn hinder widespread adoption in the U.S. Our members report that feed additive manufacturers are bypassing the U.S. market approval process in favor of processes in other countries which have a more streamlined approval process. Members also report that perceived time and cost burdens associated with regulatory approval are limiting research and development investments in this essential area in the U.S.

FACA supports FDA's efforts to explore opportunities to expedite regulation of animal drugs and feed foods which act in the digestive tract with certain types of claims and commends FDA for hosting this listening session. Our organizations believe FDA has clear authority to immediately implement measures that prioritize review of animal drugs and foods that demonstrate promising environmental benefits. For example, FDA could prioritize review of

products that have been approved in other jurisdictions such as the EU and Canada, allow Food Additive Petitions to be submitted on a rolling basis, and assign one point of contact, and engagement from senior management, to handle animal drug and food additive petitions for certain environmentally beneficial products. FDA could also streamline the development and approval process for enteric methane inhibiting products by clarifying and making transparent the protocols needed to verify product efficacy, potentially engaging expertise from other agencies such as USDA. As FDA continues its work, FACA urges the agency to prioritize consideration of those products with climate and digestive efficiency benefits, recognizing those products whose mode of action is solely within the digestive tract of animals. Our members look forward to future opportunities to assist FDA in defining suitable endpoints for categorizing such products, as well as opportunities to streamline their review to parallel processes deployed in other jurisdictions. Doing so would better align U.S. policy with that in other major developed countries that currently allow for animal feed additives to decrease the environmental footprint of food production. Streamlining the approval process would also send signals to the private sector making key research and development decisions, which may support further innovation in this area.

Thank you for your consideration of our comments. We look forward to continuing to work with you on this important environmental stewardship and GHG reduction priority.

Sincerely,

The Food and Agriculture Climate Alliance